body health in treated subjects. No new matter is involved with the amendments to the claims and no additional claims fee is known to be due.

Restriction Requirement

The Examiner has set a restriction requirement and election was requested from among Groups I-VII composition claims (Claim 1) drawn to a topical oral composition comprising one or a mixture of host response modulating agents and a pharmaceutically acceptable carrier and from among Groups VIII-XIV method claims (Claims 2-7), each drawn to a method for promoting whole body health comprising topically administering a topical oral composition comprising one or a mixture of host response modulating agents and a pharmaceutically acceptable carrier and optionally, further comprising another therapeutically active agent. Election of a genus of host response modulating agent was further required and of a single disclosed species of H2 antagonist, anti-inflammatory agent and cell redox status modifier.

Merely for the purpose of complying with the election requirements, Applicants provisionally elect, with traverse, Group VIII method Claims 2-4 and 7; H2 antagonist from among the Markush group of host response modulating agents recited in Claim 1; and cimetidine as the single species of H2 antagonist.

The restriction requirements are respectfully traversed herein.

The Examiner submits that the compositions in Claim 1 (Groups I-VII) and the methods of use in Claims 2-7 (Groups VIII-XIV) are distinct inventions, for the reason that each said composition can be used in a materially different process of using said composition. Specifically, the Examiner contends that each of the compositions as claimed can be used as an immunogen in a method of producing monoclonal antibodies as well as in a method for promoting whole body health.

Applicants respectfully submit that the present composition claim and method claims are so closely interrelated and in order to preserve unity of invention, the composition claim and the methods of use claims of said compositions should be prosecuted in the same application. The PTO examination would be simplified and duplicate searching eliminated by pursuing one as opposed to two or more applications. As the Examiner pointed out in Item 4 of the Office Action, the composition claims and method claims are related as product and process of use.

Applicants respectfully point out that Claim 1 compositions are specifically defined as topical oral compositions, which are products which in the ordinary course of usage are not intentionally swallowed for purposes of systemic administration of particular therapeutic agents, but are rather retained in the oral cavity for a time sufficient to contact substantially all of the dental surfaces and/or oral tissues for purposes of oral activity. The present invention is concerned with treating and preventing bacteria-mediated conditions in the oral cavity and thereby promoting whole body health, specifically by topically administering the present compositions to the oral cavity as opposed to systemic administration or to any other mode of administration to any other part of the body. Applicants can find no basis in the Examiner's contention that the present topical oral compositions can be used "in a materially different process" such as an "immunogen in a method of producing monoclonal antibodies". Applicants respectfully request withdrawal of the restriction requirement between composition claims and method of use claims.

Applicants also traverse the restriction requirement with respect to a single host response modulating agent and a single species of the elected host response modulating agent.

The major reason for restriction requirements is the unduly burdensome effect in searching the art for a variety of distinct species. In this instance, since the present claims are directed to topical oral compositions, searching the art would involve the body of art classified under Class 424, Subclass 49 and Subclasses 50 through 58, which are indented subclasses under 424/49. Applicants respectfully point out that Classes 424/49 through 424/58 include ALL compositions which function primarily in the normal hygiene of the oral cavity regardless of form or constituents. Further the following notes are included with the class definition of 424/49.

(1) Note. A composition intended to be employed regularly in normal mouth-care is placed herein even if the composition contains ingredients of specific value in killing micro-organisms or in the treatment or prevention of specific mouth diseases or malfunctions such as pyorrhea trench mouth, gingivitis, etc.

(2) Note. Since a dentifrice or mouthwash is generally compounded of a plurality of ingredients, some of the significant kinds of ingredients have been set out in indented subclasses 50 to 58. For a particular ingredient containing composition not specifically provided for by said indents, a search through this and the indented subclasses will be necessary.

The Examiner's attention is respectfully directed particularly to Notes (1) and (2) with regard to the class definition, which clearly indicate that compositions for the treatment or prevention of different mouth diseases or malfunctions would also be placed within 424/49 through 424/58, regardless of the ingredients of the compositions.

Therefore, the fact that the claims recite different host response modulating agents optionally in combination with additional therapeutic agents would not necessarily place a serious burden on the Examiner to search the art and to examine the entire application on the merits, even though it may include claims to independent or distinct inventions. (MPEP § 803) Applicants respectfully request withdrawal of the restriction requirement with respect to the genus of host response modulating agent and to the species of each host response modulating agent such as H2 antagonist.

CONCLUSION

Applicants respectfully request reconsideration of this application, withdrawal of the restriction requirements, and allowance of all application claims.

Attached hereto is a marked-up version of the changes made to claims by the current amendments. The attached page is captioned "Version With Markings to Show Changes Made".

Respectfully submitted,

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Version With Markings to Show Changes Made

1. A topical oral composition for treating and preventing oral cavity diseases in human and other animal subjects and thereby promoting whole body health in said human and other animal subjects, said composition comprising a safe and effective amount of a host-response modulating agent, and a pharmaceutically acceptable oral carrier, wherein said host-response modulating agent is selected from a H2-antagonist; anti-inflammatory agent, metalloproteinase inhibitor, anti-oxidant and modifier of cell redox status, vitamins and nutrients key to maintenance of a host response balance, inhibitor of activation of NF-kB, and mixtures thereof.

2. A method for treating and preventing oral cavity diseases in human and other animal subjects and thereby promoting whole body health in said human and other animal subjects, comprising topically administering to said subjects' oral cavity, a composition according to Claim 1.

3. A method for treating and preventing oral cavity diseases in human and other animal subjects and thereby promoting whole body health in said human and other animal subjects according to Claim 2, wherein said composition is in a form selected from a mouthrinse, toothpaste, tooth gel, tooth powder, non-abrasive gel, chewing gum, mouth spray, lozenge, dental implement, and a pet care product.

4. A method for treating and preventing oral cavity diseases in human and other animal subjects and thereby promoting whole body health in said human and other animal subjects according to Claim 2, wherein said host-response modulating agent is a H-2 antagonist selected from the group consisting of cimetidine, etintidine, ranitidine, ICIA-5165, tiotidine, ORF-17578, lupitidine, donetidine, famotidine, roxatidine, pifatidine, lamtidine, BL-6548, BMY-25271, zaltidine, nizatidine, mifentidine, BMY-25368 (SKF-94482), BL-6341A, ICI-162846, ramixotidine, Wy-45727, SR-58042, BMY-25405, loxtidine, DA-4634, bisfentidine, sufotidine, ebrotidine, HE-30-256, D-16637, FRG-8813, FRG-8701, impromidine, L-643728, HB-408, and mixtures thereof.

5. A method for treating and preventing oral cavity diseases in human and other animal subjects and thereby promoting whole body health in said human and other animal subjects according to Claim 2, wherein said host-response modulating agent is an anti-inflammatory agent selected from the group consisting of aspirin, ketorolac, flurbiprofen, ibuprofen, naproxen, indomethacin, aspirin, ketoprofen, piroxicam, meclofenamic acid, nordihydoguaiaretic acid, triclosan, and mixtures thereof.

6. A method for treating and preventing oral cavity diseases in human and other animal subjects and thereby promoting whole body health in said human and other animal subjects according to Claim 2, wherein said host-response modulating agent is a cell redox status modifier

selected from the group consisting of Co-enzyme Q10, PQQ, Vitamin C, Vitamin E, Vitamin A, epi-gallo catechin gallate, anethole-dithiothione, and mixtures thereof.

7 A method for treating and preventing oral cavity diseases in human and other animal subjects and thereby promoting whole body health in said human and other animal subjects according to Claim 2, wherein said composition topically administered to said subjects comprises an additional therapeutic active selected from antimicrobial/antiplaque agents, biofilm inhibiting agents, antibiotics; analgesics and local anesthetic agents; dentinal desensitizing agents; odor masking agents; and mixtures thereof.